

Frequently Asked Questions Regarding the Department of Health and Human Services' Announcement on the Unapproved Drugs Initiative

Q: What action is the Department taking today?

A: Through a [Notice published in the *Federal Register*](#), we are withdrawing guidance documents issued as part of the Unapproved Drugs Initiative that, although they originated with the laudable goal of generating more clinical data about unapproved drugs, are linked to prescription drug price increases and shortages.

Q: What are the expected benefits of this action?

A: The Department believes terminating the program will prevent actors from using Food and Drug Administration (FDA) rules to enjoy artificial monopolies over older drugs that are important to the health of Americans. This action will protect Americans from future drug price spikes and shortages.

Q: What is the Unapproved Drugs Initiative?

A: The Unapproved Drugs Initiative (UDI) was an FDA program launched through guidance documents issued in 2006 and 2011. The program aimed to reduce the number of drugs available on the market that lack FDA-approved New Drug Applications (NDAs) or Abbreviated New Drug Applications (ANDAs). The UDI created the potential for market exclusivity for manufacturers that took previously unapproved drugs through the FDA approval process.

Q: Did the program lead to adverse consequences?

A: Yes. For example, a peer-reviewed study by scholars at the Yale School of Medicine and the University of Utah found “the UDI had the unintended consequence of increasing drug prices and shortages.” The study found that the median average wholesale unit price for such drugs increased 37 percent for UDI drugs, and that 11 of 34 drugs studied increased in price by more than 128 percent. The study, published in the *Journal of Managed Care and Specialty Pharmacy*, [is available online](#).

Q: Why was the UDI created in the first place?

A: FDA created the UDI with the laudable goal of providing FDA with more data regarding older drugs.



Q: Did the UDI achieve those goals?

A: No. The aforementioned Yale study found that the program “rarely generat[ed] additional clinical evidence of safety or efficacy.” More specifically, the study, which reviewed 34 previously unapproved drugs approved by FDA between 2006 and 2015, found that manufacturers produced new clinical studies in only two cases.

Q: How did the UDI program lead to higher drug prices, in some cases by more than 1,000 to 5,000 percent?

A: The program offered drug manufacturers the opportunity to obtain “de facto market exclusivity” for older drugs that had been used safely for decades but were never brought through the FDA approval process. This market exclusivity allowed manufacturers an opportunity to raise prices in an environment largely insulated from market competition.

Q: Why is HHS taking this action?

A: Despite FDA’s laudable policy goals, the UDI has had unintended consequences, leading to price increases and drug shortages without adding substantial amounts of clinical trial data.

The Department has serious concerns that the UDI was not issued pursuant to legally appropriate procedures, because it was not issued pursuant to notice-and-comment rulemaking and there was no public comment period before the 2011 Guidance was issued. The initiative was also premised on a reading of section 201(p) of the Federal Food, Drug & Cosmetic Act (FD&C Act) that largely eliminated the exemptions from the new drug approval process enacted by Congress in 1938 and 1962.

Q: Will manufacturers of drugs subject to the program still be able to obtain regulatory exclusivity?

A: Only manufacturers of “new drugs” under the terms of the FD&C Act that meet other statutory requirements are entitled to receive regulatory exclusivity. However, the Notice does not apply to drugs subject to (1) Investigational New Drug applications (IND) that are in effect as of the effective date of this Notice, (2) any subsequent NDA based on new clinical trial investigations (other than bioavailability studies) derived under such IND, and (3) existing approved NDAs.

Q: Are unapproved drugs necessarily dangerous?

A: No. Many older drugs, such as drugs containing salicylic acid, lack approved NDAs or ANDAs, but have well-established safety and efficacy profiles based on decades of use. Further, drugs subject to FDA over-the-counter drug monograph regulations are unapproved, and are legally marketed on the basis that such drugs are generally recognized as safe and effective. See 21 C.F.R. § 330.1 (“An over-the-counter (OTC) drug listed in this subchapter is generally recognized as safe and effective and is not misbranded if it meets each of the conditions contained in this part and each of the conditions contained in any applicable monograph.”)



Q: Will this announcement result in more unapproved drugs entering the marketplace?

A: This announcement largely reverts to the regulatory status quo as it existed in 2006 with respect to FDA's approach to unapproved drugs. FDA retains the ability to take enforcement action against misbranded and adulterated drugs that present public health risks.

Q: Does this announcement mean manufacturers of unapproved drugs are not subject to FDA regulation?

A: No. Among other things, all drug manufacturers are required to register their establishments with the FDA, must list their products with the agency, and are subject to Current Good Manufacturing Practices regulations. The FDA also retains the authority to take enforcement action against drugs that are misbranded, adulterated, or otherwise endanger the public health.

Q: Does this announcement eliminate the Office of Unapproved Drugs and Labeling Compliance (OUDLC) at FDA?

A: No. FDA and OUDLC will continue to police the marketplace for violations of section 505(a) and other provisions of the FD&C Act.

Q: Will this announcement interfere with FDA's response to the COVID-19 pandemic?

A: No. Nothing in this announcement prevents FDA from protecting Americans from unapproved drugs that purport to treat, mitigate, or cure COVID-19. Further, this announcement allows FDA to devote its limited resources to reviewing innovative potential COVID-19 treatments, as opposed to reviewing older drugs with longstanding use.

Q: When does this announcement go into effect?

A: Thirty days after publication of the Notice in the *Federal Register*.

Q: Why not just make manufacturers lower the prices they charge American patients?

A: The Trump Administration is exploring all options available under the law to lower drug prices for American patients, including by increasing competition, a strategy identified in the Department's 2018 [American Patients First](#) drug pricing blueprint. Withdrawing the 2011 Guidance on which the UDI is based is a step toward ending price gouging that results from a lack of competition, because it eliminates the ability of drug companies to obtain market exclusivity under a program that has not delivered commensurate benefits.

Q: Why is this posted on HHS.gov and not on FDA.gov?

A: HHS is transmitting for official publication a Notice in the Office of the Federal Register. The Office of the Secretary has led strategic efforts to reduce drug prices, and this is an action that will deter future drug price spikes and shortages by preventing new artificial



monopolies. FDA retains the ability to take enforcement action against misbranded and adulterated drugs that present public health risks.

Q: How does this announcement impact parties that have relied on the UDI program?

A: Today's announcement does not apply to drugs subject to (1) Investigational New Drug applications (IND) that are in effect as of the effective date of this Notice, (2) any subsequent New Drug Application (NDA) based on new clinical trial investigations (other than bioavailability studies) derived under such IND, and (3) existing approved NDAs.

Q: Is the Department reducing FDA's ability to gather needed data and evidence on unapproved drugs?

A: No. As discussed above, a 2017 Yale study found that the UDI “rarely generat[ed] additional clinical evidence of safety or efficacy.” The Department has concluded the program did not generate a great deal of new data, but unintentionally imposed significant costs on Americans.

